AMENDED IN ASSEMBLY APRIL 4, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2156

Introduced by Assembly Member Niello

February 21, 2006

An act to amend Section ~~1241 of~~ *1209.1 of, and to add Section 1209.5 to,* the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2156, as amended, Niello. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services. ~~Existing law exempts specified clinical laboratories and persons performing clinical laboratory tests from those requirements.~~ *Existing law makes a violation of these provisions a crime.*

~~This bill would make a technical and nonsubstantive change to that provision.~~ *Existing law defines a "histocompatibility laboratory director" as any person who is (1) a duly licensed physician, (2) a bioanalyst, or (3) a person who has earned a doctoral degree in a biological science and has completed, as specified, 4 years of experience in immunology, 2 of which have been in histocompatibility testing.*

This bill would require an applicant for licensure as a histocompatibility laboratory director to successfully complete a written exam administered by the American Board of Histocompatibility and Immunogenetics and an oral exam administered by the department.

Existing law defines a "laboratory director" as any person that is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory and who meets specified qualifications. Existing law makes laboratory directors responsible for the overall operation and administration of clinical laboratories which includes, among other things, the reporting of results.

This bill would require a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and document explicit criteria by which clinical laboratory tests or examination results are autoverified, as defined. The bill would also require a laboratory director or an authorized designee, annually, to revalidate the criteria. The bill would require specified licensed persons to be physically present onsite in the clinical laboratory and it would make these specified licensed persons responsible for the accuracy and reliability of the results when they are autoverified and reported.

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ *yes*. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.1 of the Business and Professions Code is amended to read:

1209.1. *(a)* As used in this chapter "histocompatibility laboratory director" means ~~any~~ *a* person who ~~is (a) a duly licensed physician, (b) a bioanalyst, or (c) a person who has earned a doctoral degree in a biological science and~~ has completed, subsequent to graduation, four years of experience in immunology, two of which have been in histocompatibility testing, *and who meets one of the following requirements:*

(1) Is a licensed physician and surgeon.

(2) Is a bioanalyst.

(3) Has earned a doctoral degree in a biological science.

(b) In order to be eligible for licensure as a histocompatibility laboratory director, an applicant shall provide evidence of satisfactory performance on a written examination in histocompatibility administered by the American Board of Histocompatibility and Immunogenetics, and have demonstrated satisfactory performance on an oral examination administered by the department regarding this chapter and Part 493 (commencing with Section 493.1) of Subchapter G of Chapter IV of Title 42 of the Code of Federal Regulations.

(c) A person licensed under Section 1260.1 as a histocompatibility laboratory director and qualified under CLIA may perform clinical laboratory tests or examinations classified as of high complexity under CLIA and the duties and responsibilities of a laboratory director, technical consultant, clinical consultant, technical supervisor, and general supervisor, as specified under CLIA, in the specialty of histocompatibility, *immunology,* or other specialty or subspecialty specified by regulation adopted by the department. A person licensed as a "histocompatibility laboratory director" may perform any clinical laboratory test or examination classified as waived or of moderate complexity under CLIA.

SEC. 2. Section 1209.5 is added to the Business and Professions Code, to read:

1209.5. (a) "Autoverification" means the use of a computer algorithm in conjunction with automated clinical laboratory instrumentation to review and verify the results of a clinical laboratory test or examination for accuracy and reliability.

(b) The laboratory director or authorized designee shall establish, validate, and document explicit criteria by which the clinical laboratory test or examination results are autoverified.

(c) The laboratory director or authorized designee shall annually revalidate the explicit criteria by which the clinical laboratory test or examination results are autoverified. The laboratory director shall approve and annually reapprove the computer algorithm.

(d) An authorized designee shall be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical

laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.

(e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

~~SECTION 1. Section 1241 of the Business and Professions Code is amended to read:~~

~~1241. (a) This chapter applies to all clinical laboratories in California or those receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination, and to all persons performing clinical laboratory tests or examinations or engaging in clinical laboratory practice in California or on biological specimens originating in California, except as provided in subdivision (b).~~

~~(b) This chapter shall not apply to any of the following clinical laboratories, or to persons performing clinical laboratory tests or examinations in any of the following clinical laboratories:~~

~~(1) Those owned and operated by the United States of America, or any department, agency, or official thereof acting in his or her official capacity to the extent that the Secretary of the federal Department of Health and Human Services has modified the application of CLIA requirements to those laboratories.~~

~~(2) Public health laboratories, as defined in Section 1206.~~

~~(3) Those that perform clinical laboratory tests or examinations for forensic purposes only.~~

~~(4) Those that perform clinical laboratory tests or examinations for research and teaching purposes only and do not report or use patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or for the assessment of the health of, an individual.~~

~~(5) Those that perform clinical laboratory tests or examinations certified by the National Institutes on Drug Abuse only for those certified tests or examinations. However, all other clinical laboratory tests or examinations conducted by the laboratory are subject to this chapter.~~

~~(6) Those that register with the State Department of Health Services pursuant to subdivision (c) to perform blood glucose testing for the purposes of monitoring a minor child diagnosed with diabetes if the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and provided that all of the following occur:~~

~~(A) The blood glucose monitoring test is performed with a blood glucose monitoring instrument that has been approved by the federal Food and Drug Administration for sale over the counter to the public without a prescription.~~

~~(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.~~

~~(C) The person, receiving written authorization from the minor's parent or legal guardian, complies with written instructions from the child's health care provider, or an agent of the child's health care provider, regarding the performance of the test and the operation of the blood glucose monitoring instrument, including how to determine if the results are within the normal or therapeutic range for the child, and any restriction on activities or diet that may be necessary.~~

~~(D) The person complies with specific written instructions from the child's health care provider or an agent of the child's health care provider regarding the identification of symptoms of hypoglycemia or hyperglycemia, and actions to be taken when results are not within the normal or therapeutic range for the child. The instructions shall also contain the telephone number of~~

~~the child's health care provider and the telephone number of the child's parent or legal guardian.~~

~~(E) The person records the results of the blood glucose tests and provides them to the child's parent or legal guardian on a daily basis.~~

~~(F) The person complies with universal precautions when performing the testing and posts a list of the universal precautions in a prominent place within the proximity where the test is conducted.~~

~~(7) Those individuals who perform clinical laboratory tests or examinations, approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, on their own bodies or on their minor children or legal wards.~~

~~(8) Those certified emergency medical technicians and licensed paramedics providing basic life support services or advanced life support services as defined in Section 1797.52 of the Health and Safety Code who perform only blood glucose tests that are classified as waived clinical laboratory tests under CLIA, if the provider of those services obtains a valid certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations.~~

~~(c) Any place where blood glucose testing is performed pursuant to paragraph (6) of subdivision (b) shall register by notifying the State Department of Health Services in writing no later than 30 days after testing has commenced. Registrants pursuant to this subdivision shall not be required to pay any registration or renewal fees nor shall they be subject to routine inspection by the State Department of Health Services.~~

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